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MOSELY AND ASSOCIATES, INC.

November 25, 1998

VIA FEDERAL EXPRESS

Dr. Larry G. Hart
Board Executive Secretary
National Toxicology Program - Public Health Service
Department of Health and Human Services
111 T. W. Alexander Drive
Building 101, South Campus
Research Triangle Park, NC 27709

RE: Comments from Footwear Industries of America, Inc.
Regarding Whether Boot and Shoe Manufacturing and Repair Should
Be Referenced in the Ninth Biennial Report on Carcinogens

Dear Dr. Hart:

On behalf of Footwear Industries of America, I have attached our written comments in preparation for the meeting of the Board of Scientific Counselors of the National Toxicology Program, regarding the review of nominations for listing in or delisting from the Ninth Report on Carcinogens, to be held December 2-3, 1998, in Research Triangle Park.

The comments are prepared in two parts; first, I have included our technical comments regarding whether "Boot and Shoe Manufacturer and Repair" should be referenced in the Ninth Biennial Report on Carcinogens, and have also attached the comments prepared by legal counsel for Footwear Industries of America regarding the very serious legal issues we feel surround this issue.

As mentioned in previous discussions which Kate McMahon and Lauren Howard have had with you regarding FIA's concerns, we will be presenting a formal presentation before the RoC subcommittee on Thursday afternoon, December 3, 1998, in Research Triangle Park. We understand we are scheduled as the last nomination to be reviewed, and are tentatively scheduled for late that Thursday afternoon. We plan to arrive there at the South Campus at approximately 1:00 PM in order to be present when we are called. If there is a rescheduling wherein our Thursday afternoon time slot will be changed, I would appreciate a telephone call to my offices at (800) 728-1016 in Nashville, Tennessee, so we may change our travel schedule.

I look forward to seeing you again next week at the subcommittee meeting.

Sincerely yours,

Ralph E. Mosely, CSP
Technical Consultant to Footwear Industries of America, Inc.

REM/db
Enclosures

cc: Fawn Evenson - President - Footwear Industries of America, Inc.
Kathryn M. T. McMahon, Esq. - Collier, Shannon, Rill and Scott, PLLC

COMMENTS OF

RALPH E. MOSELY
ON BEHALF OF
FOOTWEAR INDUSTRIES OF AMERICA, INC.

REGARDING WHETHER
"BOOT AND SHOE MANUFACTURE AND REPAIR"
SHOULD BE REFERENCED IN THE
NINTH BIENNIAL REPORT ON CARCINOGENS

MADE BEFORE THE

NATIONAL TOXICOLOGY PROGRAM,
U.S. PUBLIC HEALTH SERVICE
DEPARTMENT OF HEALTH AND HUMAN SERVICES

DECEMBER 3, 1998

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Attachment 1

TECHNICAL COMMENTS OF RALPH E. MOSELY
ON BEHALF OF FOOTWEAR INDUSTRIES OF AMERICA
Regarding whether "Boot and Shoe Manufacture and Repair"
should be referenced in the Ninth Biennial Report on Carcinogens

I. INTRODUCTION.

Good afternoon. I'm Ralph Mosely, and I am appearing here today on behalf of Footwear Industries of America, Inc. ("FIA"). FIA is the trade association representing U.S. manufacturers of nonrubber footwear, importers/distributors, and a substantial number of suppliers to the leather trades.

I have provided NTP with my curriculum vitae describing my background as a safety professional and industrial hygienist who has worked with the domestic shoe manufacturing industry for over twenty years. I am a Certified Safety Professional and have been involved with professional safety and industrial hygiene activities in both industry and in education since 1966. I served for over ten years as the Corporate Director of Employee and Environmental Safety for Genesco Inc., one of the nation's largest footwear manufacturers, and for another eleven and one-half years as the President of Mosely and Associates, Inc., an industrial and environmental safety consulting firm based in Nashville, Tennessee. I also have taught courses in industrial hygiene, hazardous materials, safety management and other safety related areas for seven years as an Associate Professor in the Schools of Engineering at Tennessee State University and at the University of Tennessee at Nashville. I have written or edited four books on industrial safety and have served for many years with several professional safety organizations, including the Executive Committee and Board of Directors of the National Safety Council. I am listed in "Who's Who in Science and Engineering."

"Who's Who in the South and Southwest" and in "Emerging Leaders in America" and several other similar listings for the safety activities in which I have been involved.

I would like to begin by thanking Dr. Hart, Dr. Jameson, and others at NTP for allowing FIA the opportunity to participate in this meeting today, and to submit written comments on whether boot and shoe manufacturing and repair processes should be listed or referenced or delisted in the Ninth Biennial Report. FIA fully supports the recommendation of NTP's RG2 Working Group that, because "available data are insufficient to characterize either the exposures or the risks entailed by employment in the U.S. industry," the boot and shoe manufacturing industry should not be listed in the Ninth Biennial Report.

Dr. Jameson of NTP has explained to FIA that NTP recently developed new procedures for reviewing substances and occupational exposures. Under the new procedures, NTP identifies all occupational exposures and substances reviewed for inclusion in its Reports in an appendix to the Report, with the intent that the public be fully informed as to the industries and substances reviewed. FIA does not oppose identification of our industry in an appendix designed to identify those industries reviewed for inclusion in the report, as long as the appendix is written in manner that does not misrepresent NTP's ultimate finding that available data does not establish sufficient exposures or risks to warrant listing our industry in the Report.

I recognize that this Committee has an obligation to independently evaluate the data upon which the previous committees relied in making their determination to not list our industry in the Ninth Biennial Report. Accordingly, I believe it is important that I provide an assessment and evaluation of the data included in NTP's Background Document on the Boot and Shoe Industry, as

well as review the conclusions of our own studies of these, and other, data from our ongoing research since the mid-1980s.

First, the Background Document recognizes that many of the agents identified in the studies and assessed in the Document are no longer used in the U.S. industry. Our industry has long been frustrated that NTP has in the past failed to recognize the critical importance of this fact. FIA is very pleased that the Background Document seems to now recognize that the foreign studies demonstrating cancer -- to the extent they do -- associated with agents and/or processes never or no longer used in the U.S. industry are irrelevant concerning whether U.S. employees are exposed to an increased risk of cancer from their occupation in our industry.

Second, as you know, until this year, NTP has relied exclusively on the studies also relied on by the International Agency for Research on Cancer (IARC) to support its inclusion of the boot and shoe industry in its Annual Reports. This year, however, NTP's Background Document recognizes additional studies conducted since the IARC Monographs on this industry were published (in 1981 and 1982). These studies, many of which have been conducted in U.S. shoe manufacturing plants, demonstrate clearly that the IARC pre-1981 studies conducted in foreign footwear manufacturing plants bear no resemblance in potential worker exposures to modern, OSHA-regulated, U.S. footwear plants. The adhesives in our U.S. plants are either water-based or "hot-melt" (non-toxic) adhesives or, if solvent-based, the solvents used are not the benzene-based adhesives and cleaners found in many of the old foreign studies. Many of the foreign studies also termed dust and solvent ventilation systems "inadequate". Since 1971 in the U.S., OSHA regulations have mandated that ventilation systems remove contaminants from the workplace.

Additionally, U.S. work methods involve automated and semi-automated processes, whereas the IARC studies involved foreign factories where most work was performed by hand.

Third, the original basis for NTP's review of the boot and shoe manufacturing industry was the IARC Monograph, Volume 25, published in 1981, and the IARC Monographs Supplement 4, published in 1982. I provided comments critiquing the individual studies relied on by IARC in these two Monographs, both in 1987 when I testified before your committee in Washington regarding the Draft Fourth Annual Report, and again two years ago when I commented before your committee on the reference to our industry in the Draft Eighth Biennial Report. Because these studies still seem to be driving the concern about potential carcinogenic risk associated with boot and shoe manufacturing, I have included many of my previous comments on those studies below.

The bottom line is that neither the studies relied upon by IARC or the studies conducted since the 1981-82 time frame establish a causal link between the modern, OSHA-regulated footwear industry in the United States and cancer. Let me explain further, below:

II. POST-IARC STUDIES.

Rather than review each post-1981 study conducted in U.S. Footwear manufacturing plants to determine worker exposure to chemicals, or to review whether epidemiological data suggests a higher than expected death rate due to certain diseases, I believe the following summary can point out why these studies also bear no relevance to modern, OSHA-regulated, U.S. footwear manufacturing plants.

First, of the twelve NIOSH Health Hazard Studies listed in the "Draft RoC Background Document for Boot and Shoe Manufacturer and Repair" (Section 2.1), eleven were conducted prior

to 1983, over 15 years ago. The only one conducted within the last decade (U.S. Shoe. Ohio. 1991) was conducted in 1991 and concluded that the airborne concentrations of all chemicals sampled were below both OSHA Permissible Exposure Limits (PELs) and NIOSH Recommended Exposure Limits (RELs). Those authors further concluded that the current chemical exposure levels in the facility did not appear to have appreciable cancer-causing potential.

The NIOSH Occupational Exposure Data (Section 2.2) presented in the Draft RoC Background Document, contained data on studies conducted from 1972 to 1974 and from 1981 to 1983, again, the latest data being 15 years old. Furthermore, the 1981 to 1983 data was conducted in plants producing rubber and plastic footwear or children's footwear including vulcanized rubber. In addition to that data being old, the rubber and plastic footwear segment of the U.S. Footwear manufacturing industry (not represented by the Footwear Industries of America) is extremely small, with the vast majority of all such footwear now being produced overseas.

Exposure Data from U.S. Epidemiology Studies (Section 2.3) of the Document, again relates to solvent exposures that were measured in 1977-1979, and comments on a 1940 survey of the U.S. leather industry; both of which involve conditions in manufacturing plants that certainly cannot be considered "modern". In the most recent study in that group by Decouflé and Walrath (1987), they suggest that the U. S. manufacturing processes may be different and that working practices may differ in the following areas from the studies they conducted in England; use of protective clothing, dust control mechanisms, housekeeping practices, and personal hygiene habits. They are correct in their suggestion.

In Air Emissions from U.S. Footwear Manufacturing Plants (Section 2.4), 20 of the 24 chemicals listed occurred in SIC Code 3021 plants, (rubber and plastic footwear), rather than in regular types of footwear manufacturing plants, including those utilizing leather.

Concerning human studies published post-IARC or after 1981 (Section 3.2), all of the studies involved periods of time that were many decades ago. Admittedly, epidemiology studies must wait for an individual to die before the data can be included, but it must be pointed out again that such studies were not accomplished when the workers included in those studies were employed in modern, U.S., OSHA-regulated footwear manufacturing plants.

Concerning the additional sections of this report, Experimental Carcinogenesis, Genotoxicity, Other Relevant Data, and Mechanisms of Carcinogenesis (Sections 4.0 through 7.0), no studies or information were relevant to modern, U.S., OSHA-regulated footwear manufacturing plants.

In summary, it is not surprising that more data, particularly recent data, was available for inclusion in this review. By the very nature of the purpose of such studies, researchers tend to concentrate in those areas where problems are suspected. Since the more recent studies of U.S. footwear manufacturing plants, (and even the older studies, too) have concluded that worker exposure to chemicals is not significant and that there does not appear to be a link between occupational cancers and worker exposure in modern, U.S., OSHA-regulated footwear manufacturing plants, then there does not appear to be a crucial need for additional research to be conducted in our industry.

III. STUDIES RELIED ON BY IARC.

The IARC Monographs relied upon by the NTP are inadequate as a basis of listing the footwear industry in its reports because all of their supporting references contain one or both of the following attributes. First, information about the occupational and personal health histories of the subjects is insufficient to identify the probable causes of the cancers. The references contained little or no information on the smoking or snuff habits of the studies' subjects, even though such information was considered important. There was also little or no information about other environmental exposures to carcinogens, long term employment histories, diet or other health habits.

Second, and equally as important from a researcher's point of view but much more important if you are a worker in an American footwear manufacturing plant, the working conditions studied differ in significant and relevant ways from those found in modern, U.S., OSHA-regulated boot and shoe manufacturing facilities. Many of the studies referenced foreign manufacturing processes which involved chemicals and conditions not found in today's domestic manufacturing industry. For example, the excessively dusty environments described in certain operations in foreign facilities do not exist in United States plants. Also, several studies involved highly toxic chemicals long ago banned here in our country.

IARC studies, by the very nature of their international focus, are not an appropriate basis for linking United States industries and industrial processes to cancer. While the effects on an individual of their exposure to a substance or chemical should not vary in different countries, a similar analogy cannot be made reliably with respect to industries. Because the processes and chemical exposures in an industry can vary immensely from one country to the next, international industrial studies yield no reliable conclusions about the relative risk of cancer in the United States.

The following sections will discuss in some detail why studies of shoe manufacturing processes in England, Holland, Turkey, Italy and elsewhere, as well as why studies based on outdated domestic processes, cannot support the conclusion that there is an association between cancer and today's boot and shoe industry in the United States.[1]

A. Mesothelioma

IARC's latest reference associating a specific cancer with the footwear industry states: "three cases of mesothelioma were reported among 3,806 deaths in shoe workers, there was an earlier report of a female shoemaker (whose husband was also a shoemaker) who died of mesothelioma". See the Supplement at pg. 138. The statement is based on work by Decouflé and by Vianna and Polan, respectively.[2]

Mesothelioma is a rare type of cancer which may be caused only by an exposure to asbestos fibers. The 1980 report by Decouflé was limited to a review of 3,806 death notices published during the period 1966-77, where "shoemaker" was listed as the last known occupation. During this eleven-year period, the average yearly number of shoe workers employed in the industry was 194,000. From this population, the death notices revealed three deaths from mesothelioma.

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[1] It cannot be overemphasized that the various, references cited in the IARC Monographs focused on specific conditions that do not exist in the United States boot and shoe industry. Also, many of the reports stated that no conclusion could be drawn from their findings. A representative compilation of limiting statements, of the sort referred to here, is contained in the chart at the end of these comments.

[2] See Decouflé, P. (1980) "Mesothelioma Among Shoe Workers" and Vianna, N. J. and Polan, A. K. (1978) "Non-Occupational Exposure to Asbestos and Malignant Mesothelioma in Females." See also IARC Supplement 4 at 138-139.

Decouflé's paper acknowledges that he was unable to confirm the diagnosis of mesothelioma. He also was unable to investigate the nature of other types of employment the three shoe workers might have had. The individuals are identified in the study as "A," "B," and "C." Individual A was a female, 72 years old at the time of death, whose first year of employment in the shoe industry was 1923. No other information, including the duration of her employment in the shoe industry or the types of jobs that she may have had, is known about her. Worker B was a male who died at the age of 60. The date of his initial employment is unknown. Worker C, a female who died at age 72, began her employment in 1926 and continued as a shoe worker in the industry for 41 years, until 1967. The duration of A and B's employment in the industry, as well as A, B or C's possible non-shoe related employments, are unknown. Whether these workers were employed in an asbestos-related industry during their careers is not stated on their death notices. However, since they worked in very old plants, dating from before the 1920's, it is possible that they were exposed to asbestos from factory insulation materials. Similarly, environmental exposures to asbestos outside the workplace are unknown.

Decouflé states that he knows of no specific source of asbestos exposure in the shoe industry. He speculates that asbestos filler may be used in rubber soles and heels. Our research shows that asbestos has not been used for these products within at least the last 30 years and that asbestos was probably never used at all. Certainly, today's shoe industry uses no asbestos. Thus, there is no basis on which to expect any association of mesothelioma with modern footwear factory conditions in the United States.

The study by Vianna and Polan specifically focused on non-occupational exposures to asbestos. Their report concluded that "the possibility of a genetic predisposition to malignant mesothelioma" may have been the link to cancer in the studies' subjects. The study acknowledges

that the hazards of exposure to asbestos in the general environment is unclear. It recites numerous reports of mesothelioma detected in individuals exposed to asbestos dust from dusty clothing and from asbestos air pollution in the neighborhood. The Supplement cites to only one individual found to have mesothelioma who was also a shoemaker: a female who died at age 85 in 1974. Although neither the Supplement nor the study explains where asbestos exposure may have been found in a shoe factory, the Supplement asserts without explanation that "shoemaker" is an occupation where there is exposure to asbestos.

There is no evidence that asbestos was ever used in the manufacturing of shoes in the United States. Certainly, asbestos is not used in any way in the manufacture of shoes in the United States today. We believe that no fair or reasonable conclusion can be drawn from the Decouflé or Vianna and Polan studies that mesothelioma is associated with shoe manufacturing in the United States. Indeed, the studies themselves draw no such conclusion.

B. Nasal and Lung Cancer

The Report states that "Employment in the boot and shoe industry is causally associated with the development of nasal adenocarcinomas" See the Monograph at page 274. The Monograph reference cited in support of this proposition relies primarily on reports published by E. D. Acheson, a researcher who was primarily interested in nasal cancers discovered in woodworkers, which he believed resulted from exposure to wood dust

His investigation of woodworkers led to an examination of shoemakers in Northamptonshire, England, in the 1950's through the 1970's. At that time, wood fiberboard was used extensively in the Northamptonshire shoe industry. Wood products are rarely used in the United States shoe industry today, and the limited amount of products that are used come to the shoe factory pre-

processed, shaped, beveled and ready for use As a result, shoe factories in the United States have no wood dust in their environment.

Similarly, papers that speculate on the existence of a link to cancer from leather dust were undertaken in foreign plants where "extremely dusty" conditions prevailed. Due to stringent OSHA regulations in the United States, domestic workers are protected against exposure to dusty or fume-filled environments through the use of venting and exhaust equipment. Moreover, the use of leather soles has steadily and substantially declined in the domestic industry since the end of World War II. See, the Monograph at page 255. Cutting and grinding of leather soles in English shoe factories was reported to have produced the most dusty conditions in the manufacturing process but are likely not even present in England today. Thus, Acheson concludes:[3]

> It is important to point out that the environmental conditions which gave rise to the cases of intranasal cancer reported in this paper existed in the industry many years ago.

The following is a summary of important points presented in the referenced articles used to support IARC's conclusion of a link between nasal cancer and the boot and shoe industry. Note that the studies used limited sampling with no history on the subjects' use of tobacco or snuff even though

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[3]Acheson, E. D., "Nasal Cancer in the Furniture and Boot and Shoe Manufacturing Industries." Preventive Medicine 5 (1976), at 295. Acheson describes at 308 of his study that among the dustiest jobs in the shoe factories were: (1) sorting leather in the rough stuff room; (2) the revolution process of operating insole surface scouring machines; and (3) heel and sole trimming and scouring.

The "rough stuff" room was the location where sole leather was sorted from the tannery before using. Today, in the U.S., many soles are already pre-cut when they reach the factory, and the "rough stuff" room does not exist. The operations referenced all relate to cutting or grinding functions with leather soles, not uppers. Upper leather is tanned through a different process than is sole leather, however, all cutting or grinding operation in U. S. shoe factories are subject to OSHA's strict rules on ventilation and dust capture. Also, because the use of leather soles has declined, any problem associated with dust from related operations is also diminished.

such use was considered important. The articles also focus on exceedingly dusty (frequently wood dust) and dirty conditions that are nonexistent in today's U.S. shoe factories:

1. Acheson, E. D., "Nasal Cancer in the Furniture and Boot and Shoe Manufacturing Industries," Preventive Medicine 5, 295-315 (1976)

   (a) The article reports cases diagnosed between 1950-1974 in Northamptonshire, England. Pg. 309.

   (b) Fourteen of the twenty patients examined worked in the dustiest operations. "The analysis of the location of the cases within the industry very much strengthens the evidence in favor of a causal relationship between the inhalation of dust associated with the manufacture of boots and shoes and nasal cancer." Pg. 311.

   (c) "The material therefore suggests that the excess of nasal cancer extends to these men who often work in small shops under dusty conditions without adequate ventilation." Pg. 312.

   (d) Snuff "may be a contributory factor and deserves further study." Pg. 313.

   (e) Acheson concludes that nasal cancer was a risk for men who "are concerned with the dusty operations used in the manufacture and repair of leather footwear."

   (f) He states that many changes have now been made in ventilation and hygiene. Pg. 314.

2. Acheson, E. D., Cowdell, R. H., and Jolles, B., "Nasal Cancer in the Northhamptonshire Boot and Shoe Industry," Br. Med. J., i, 385-393 (1970)

   (a) The study covers only 1953 to 1967. Pg. 385.

   (b) The study suggests a causal relationship with dust and a possible link with wood products through "vegetable infusions from wood, bark, fruit, leaves, galls, etc., USED in tanning leather for soles and heels." Pg. 390.

   (c) It references the Debois (1969) study of 29 cases of nasal cancer, two of which were shoemakers, as the "only reference which we have found to nasal cancer in workers in the footwear trades." Pg. 391.

3. Acheson, E. D., Cowdell, R. H., and Rang, E., "Adenocarcinoma of the Nasal Cavity and Sinuses in England and Wales," Br. J. Indus. Med., 29, 21-30 (1972)

Summary -- Same data as Acheson study (1970) except for one case from Wales that was added.

4. Cecchi, F., et al., "Adenocarcinoma of the Nose and Paranasal Sinuses in Shoemakers and Woodworkers in the Province of Florence, Italy (1963-77)," Br. J. Indus. Med., 37, 222-225 (1980)

Study of cancers of the nose and paranasal sinuses of both shoemakers and woodworkers from Florence, Italy, identified between 1963 and 1977.

(a) "Much of the shoe manufacturing is done in small establishments and home work shops." Pg. 222.

(b) Only seven shoemakers were in study (only three woodworkers). Of the seven, five were "heavily exposed to leather dust" Summary emphasizes heavy "intensity of exposure (probably not less than 10 hours a day six days a week) and the poor ventilation of the work rooms." Pgs. 223-224.

5. Debois, J. M., "Tumors Found in the Nasal Cavities of Woodworkers," Tijdschr. v. Geneeskd., 2, 92-93 (1969-Lemish)

Thirty workers were examined between 1958-1968. Only two were listed as "shoemakers." No mention was made of exposure duration. Since this was a study of "woodworkers," and the study is Flemish, we may assume that wooden shoes are being made.

6. Decouflé, P., "Cancer Risks Associated with Employment in the Leather and Leather Products Industry," Arch. Environ. Health, 34, 33-37 (1979)

The study concerned leather workers, shoe workers and shoe repairers, and incorrectly theorized exposure to hexavalent chrome in the tanning process (trivalent chrome is the standard tanning valence) along with exposure to azo dyes, various amines and syntans that could be the cause of cancers found among workers in the leather industry. (Note that the study lacked any exposure data on the chemicals to which it cited).

7. Delemarre, J.F.M. and Themans, H.H., "Adenocarcinoma of the Nasal Cavities," Ned. T. Geneeskd., 115, 688-690 (1971)-(Dutch)

The translation of this Dutch report appears to indicate that of the 16 patients studied from 1965-1968, only one was a shoemaker, but his job was to shape/finish/smooth Dutch wooden shoes.

8. Lobe, Von L.P. and Ehrhardt, H. P., "Adenocarcinoma of the Nose and Paranasal Sinuses - An Occupational Disease in Workers in the Wood Industry," Dtsch. Gesundheitswes, 33, 1037-1040 (1978)-(German)

The study concerned woodworkers. Table 5 contains the only mention of shoe making, but even that reads "shoemaker, wood grinder", so we may assume again that wooden heels or soles or entire shoes were being made and the exposure was to wood dust, not leather dust

9. Menck, H. R., and Henderson, B. E., "Occupational Differences in Rates of Lung Cancer," J. Occup. Med., 18, 797-801 (1976)

The study concerned lung cancer in Los Angeles County for those who died from 1968-1970 (2161 deaths) and 1,777 lung cancer deaths from 1972-1973. Although some limited references are made to leather products and shoe repairing, there is no reference to boot or shoe manufacturing.

C. Hematopoietic and Lymphoreticular Cancer

The Supplement states that "the occurrence of leukemia and aplastic anemia among shoe workers exposed to benzene is well documented." See the Supplement at page 139 and the Monograph at page 274. Of the papers cited in the IARC Monographs relating to hematopoietic and lymphoreticular cancer, Volume 25, previously referenced, and volume 29, Benzene, pages 93 - 148, published in 1982, both deal with exposure to benzene.

Briefly stated, these articles are statistical studies of benzene as a causative factor in certain blood diseases such as leukemia and aplastic anemia. All were written in the mid-to-late 1970's (except Di Bosco - 1964) and the effects on workers of the ban on benzene was by then just being noted.

Although this fact was acknowledged in the Monograph, it was given little weight or emphasis.[4] This is surprising considering the radical turnabout that appears to have occurred as a

[4]See Monograph Volume 25, p. 271.

result of the benzene ban. In fact, it could be argued that in view of the more current findings, this older data now warranted nothing more than a footnote reference.

As mentioned in our earlier comments, benzene has not been used in the United States boot and shoe manufacturing industry for probably at least 25 years. Consequently, there can be no concern of benzene-related cancer arising from the domestic boot and shoe manufacturing industry today.[5]

D. Bladder Cancer

The Supplement asserts "There is evidence of an increased risk of bladder cancer associated with employment in the leather industry. Although boot- and shoemakers were included in these studies, it is not possible to determine whether the risk related to them in particular or to other occupational subgroups." See the Supplement at page 138. Studies relied on by IARC concerning bladder cancer conclude that it may be associated with heavy smoking and with exposure to liquid

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[5]The five papers discussed in the Monograph are as follows: (1) Vigiliani and Forni (1976) "Benzene and Leukemia." The article studies the exposure of benzene to acute and chronic leukemia. The only reference to the footwear industry states that "the most convincing cases of benzene leukemia are those occurring in factories where there were outbreaks of chronic benzene poisoning." The study concluded that in another industry in which the use of benzene as a solvent had been suspended in 1964, no new cases of aplastic anemia or leukemia had been detected. (2) Vigiliani (1976) "Leukemia Associated with Benzene Exposure." In this article, Vigiliani again notes that possible benzene-related leukemia was evident in shoe workers prior to the banning of benzene as a solvent for inks and glues in Italy in 1963. (3) Mazzella Di Bosco (1964) "Considerations on Some Cases Benzol Induced Leukemia Occurring in Shoe Factory Workers." This paper was translated from Italian by faculty members of the State University of New York at Binghamton. The paper studies only leukemia cases which arose from the possible association with benzene in the workplace prior to the 1963 ban on benzene in Italy. (4) Aksoy, et al (1976) "Types of Leukemia in Chronic Benzene Poisoning -- A Study of Thirty-Four Patients"; and (5) Aksoy and Erdem (1978) "Follow-up Study on the Mortality and the Development of Leukemia in 44 Pancytopenic Patients with Chronic Exposure to Benzene." These reports review workers in Turkey who were subjected to extremely high concentrations of benzene over periods of up to 15 years under conditions that do not, and probably never have, existed in the United States.

or paste dyes used by shoe repairers in small shops.[6] There is absolutely no link asserted to shoe manufacturing. Because the manufacturing and repairing industries are distinct segments of the broader leather products industry grouping, the Report should make clear that there is no evidence of risk of bladder cancer in the U.S. shoe manufacturing industry.

E. Other Cancers Not Previously Specified

The Supplement comments on several hypotheses - generating surveys that have suggested associations between boot and shoe manufacture or repair and cancers of the lung, oral cavity and pharynx and stomach, but states that "in view of the design of the pertinent studies", these findings could not be evaluated. See the Supplement at page 139.

The Monograph also referenced a study by Versluys in 1949 and two studies by Decouflé, et al (1977 and 1979), but those studies were hampered by insufficient work histories. For example, persons were included that had, at any time, worked as "shoehands", "shoemakers", or "shoe repairers". These results were incidental to the studies' main purposes. Again, the Monograph itself states that "these findings cannot be evaluated". See the Monograph at page 274.

F. Miscellaneous Comments About the IARC Reports

The two IARC reports, the Supplement and the Monograph make no assertion of a cancer link to the industry other than for the specific types of cancers discussed above, which were supported by references to production processes and environmental conditions that are substantially different from those that exist in the modern U. S. boot and shoe manufacturing industry.

The Supplement contains no information at all concerning worker exposure to agents or processes linked with cancer. The Monograph, in its section entitled "Qualitative and Quantitative

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[6]The studies linking bladder cancer to the overall leather industry is Veys, C.A. (1974) and Widner, et al (1963), neither of which assert a link between bladder cancer and the shoe manufacturing industry.

Data on Exposures", has a table of one survey of dust concentration levels and particle sizes done in a UK plant in 1976 and a listing of chemicals that "are or have been found" in boot and shoe manufacturing plants. Many involve chemicals that have not been used in U.S. plants in decades, if at all, and the only data regarding worker exposure to chemicals came from a UK study that did not list reference information regarding a date or specific location. Interestingly, it reported that the only levels of "solvent vapors" in excess of permissible levels were those associated with exhaust ventilation systems rated "poor" or "none". This study obviously was accomplished some time prior to the date the Monograph was published (1981). Modern footwear manufacturing plants, and particularly those in the United States, have stringent exhaust ventilation requirements under OSHA regulations so that exposure to dusts or solvent vapors is minimal or non-existent.

In the absence of substantial and reliable evidence that U.S. shoe workers are today exposed to substances that are specifically listed by NTP as carcinogenic, the Boot and Shoe Manufacturing Industry should not be listed, even in the Introduction or in an Appendix, as a carcinogenic industry or process.

IV. CONCLUSION.

FIA appreciates this opportunity to provide its comments as this Committee reviews the recommendation of NTP's Working Group not to list the boot and shoe manufacturing and repair industry in the Ninth Annual Report on Carcinogens.

FIA believes strongly that its members will be irreparably harmed if this Report lists *or discusses in any way* the Boot and Shoe Manufacturing Industry, either in introductory comments, the body of the Report itself, or in an Appendix. NTP is well aware that many federal and state health, safety and environmental initiatives are launched from NTP findings. These regulatory initiatives vary from such actions as the Occupational Safety and Health Act's ("OSHA") Hazard

Communications Standard to numerous state safety regulations. Liability insurance costs and toxic tort lawsuits are also driven, in part, by NTP findings. It is critical, therefore, in carrying out its mission -- and certainly everyone recognizes that NTP has an essential mission -- that NTP examine very closely the evidence it cites in connection with any substance or industrial process being associated with cancer. Even tentative findings by NTP in any of its official publications can lead to costs and other ramifications so great that scores of factories could close.

FIA feels strongly that a comprehensive review of the data that has been generated to date that applies to modern, U.S., OSHA-regulated footwear manufacturing plants, does not support a decision for listing the boot and shoe manufacturer in the Ninth Biennial Report. In fact, we feel that the data actually supports a removal of the boot and shoe industry from any mention at all in the Report. We understand the NTP RG2 Working Group's desire to show the industry as "having been reviewed, but not formally listed, because available data are insufficient", but we are in hopes that considerable thought will be given to how that information is conveyed to the public.

We would suggest that any identification in any part of the Report, even in an appendix, should in no way create an impression that occupational exposures in today's domestic footwear manufacturing industry pose a risk of cancer. There simply is no evidence of an abnormal association of cancer with the modern boot and shoe industry in the United States.

Thank you very much for your time.